THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION This document relates to: *All Actions*	No. 1:19-md-2875 Honorable Renée Marie Bumb Special Master Thomas I. Vanaskie

PLAINTIFFS' BRIEF IN OPPOSITION TO ZHP'S OBJECTIONS TO AND MOTION TO REVERSE SPECIAL MASTER ORDER 98

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PRELIMINARY STATEMENT

ZHP's dismissive whitewash of SMO 98 seeks to minimize gross discovery violations, including the failure of the company to produce its Chairman, who was proven to have substantive knowledge and involvement directly relevant to the issues in the case, for a Court ordered deposition. The motion should be denied.

SMO 98 imposed appropriate sanctions for ZHP's failure to comply with Orders compelling significant discovery, including : (1) the deposition of Baohua Chen—ZHP's Chief Executive Officer, General Manager, and Founder—who served as the linchpin of its development, manufacture, sale, and recall of contaminated valsartan, (2) the full production of the custodial file of Baohua Chen's chief of staff, Xiaofang (Maggie) Kong, (3) the production of all native drafts, including metadata, of the internal ZHP report investigating the contamination of an irbesartan formulation ZHP was developing, with a nitrosamine, and the failure to produce the July 27, 2017 email in its native form with the required metadata.

The July 27, 2017 email from Jinsheng Lin, Ph.D. of ZHP's Center of Excellence for Modern Analytical Technologies (CEMAT), was sent to eleven high-level ZHP employees from numerous departments, including Dr. Lin's boss Min Li, Ph.D., Linda Lin (Director of Regulatory Affairs), Jucai Ge (Director of API Quality Assurance), and Peng Dong (Deputy Director of Technology), all 30(b)(6) witnesses

in this case. Importantly, Dr. Li and Linda Lin both reported directly to Baohua Chen, as the other recipients' superiors did as well.[1] The email stated in part:

> [A]fter the improvement, there is an **unknown impurity of about 0.544% at 26 minutes in the crude irbesartan**, and it is the largest impurity in the irbesartan crude product.
>
> * * *
>
> Through the secondary mass spectrometry analysis, it can be inferred that the extra NO substituent is in the cyclic compound fragment, and it is **very likely that it is an N-NO compound**; **it is similar to the N-nitrosodimethylamine that occurs in valsartan when quenched with sodium nitrite, and its structure is very toxic.**
>
> * * *
>
> **If it is confirmed as the above speculated structure, then its toxicity will be very strong, and there will be an extremely high GMP risk. This is a common problem in the production and synthesis of sartan APIs. It is recommended to improve other quenching processes (such as NaCIO) along with the optimization of the valsartan sodium azide quenching process.**

[1] The email was produced in Min Li's custodial production as a PDF copy from Min Li's laptop, instead of its native form with usable metadata as required by the ESI Protocol (4/20/2021 Min Li Dep. 97:7-98:9, Ex. 48; ECF 139; the Metadata for ZHP00190573, Ex. 50). It was not produced in any other custodian's file, and no other person was listed as a duplicate custodian—the only reasonable explanation being that the document was not supposed to be produced but slipped through. (4/20/2021 Min Li Dep. 160:8-16).

(ZHP 296 (Plaintiffs' translation) (emphasis added), Ex. 37).[2]

ZHP's tortured efforts to re-engineer the email, as if the email does not say there is NDMA in valsartan caused by the sodium nitrite quenching, fall flat. (ZHP Br. 11-12). ZHP forgets that it has also provided a translation of the email, also stating that the valsartan was contaminated with NDMA, the root cause of quenching with sodium nitrite, and the other relevant points. (Ex. 53). Moreover, ZHP has explicitly adopted this translation: in testifying on behalf of the company, ZHP 30(b)(6) witness Min Li, who holds a Ph.D. in organic chemistry from Johns Hopkins and was Dr. Lin's boss, also confirmed the content of the email during his 30(b)(6) deposition. (Min Li 4/20/2021 Dep. 82:11-12, 87:19-88:7, 88:13-89:18, Ex. 48 (discussing ZHP-295, Ex. 54)).

The circumstances also make perfect sense since Dr. Lin was in charge of CEMAT's Research Laboratory of Process and Degradable Impurities. A ZHP document described his responsibilities, and knowledge of the NDMA contamination of the ZHP valsartan and the root cause was directly within his role. (ZHP 432 (stating in part: "The main tasks of this research room are to ... study the mechanism for formation of process impurities, study the degradation path of

[2] Despite his knowledge regarding the existence and root cause of the NDMA contamination of ZHP's valsartan, no litigation hold was directed to Dr. Lin, raising significant issues - especially since the July 27, 2017 email was not in his custodial file, nor was he listed as a duplicate custodian. (Declaration of Pei Zhang Verifying ZHP's Distribution of Its Litigation Holds, Ex. 47).

degraded impurities, find effective means of controlling impurities...."), Ex. 38). Thus, it was his job to say exactly what he stated in his email, which he sent to Min Li, who reported directly to Chairman Chen—it takes a very small step rather than a leap to infer that Min Li would not have kept such important information from Mr. Chen. The Special Master's focus on this document was absolutely reasonable and appropriate. The other documents discussed in SMO 98 directly relate to the issues addressed in the July 27, 2017 email as well.

SMO 98 flows directly and logically from the Court's prior decision rejecting ZHP's effort to capitalize on Chinese "blocking statutes" to avoid its obligations under the Federal Rules of Civil Procedure. In light of the Special Master's careful and thorough reasoning, the Court should affirm SMO 98.

PROCEDURAL HISTORY

SMO 98 is the culmination of years of difficult litigation. As recited in SMO 98, ZHP made every effort to block Plaintiffs from taking the deposition of ZHP Chairman Baohua Chen, requiring Plaintiffs to battle through a string of obstructive motions and objections. On December 31, 2020, the Court ruled that Baohua Chen was a proper deponent, (ECF 704). The Parties ultimately scheduled Baohua Chen's deposition for May 31, 2021. Then, after waiting months, on May 17, 2021, ZHP filed a motion for a protective order to preclude the deposition. (ECF 1247). On June 15, 2021, the Court ordered ZHP to produce Baohua Chen's custodial file for use in his deposition. (ECF 1315). On June 22, 2021, Special Master Vanaskie denied the

motion for protective order. (ECF 1330). Special Master Vanaskie postponed Baohua Chen's deposition to allow ZHP's motion to Judge Kugler to be filed and ruled upon. (6/25/2021 Tr. at 6:23:23-25, 11:1-8). ZHP filed its objection on July 13, 2021. (ECF 1386). Judge Kugler denied ZHP's motion. (ECF 1453, 1472, 1475).

On October 26, 2021, ZHP first disclosed that "due to his governmental responsibilities, the Chinese government has verbally denied Baohua Chen's request for a permit to travel to Macao to be deposed in this action." (ECF 1673, p. 1-2). At the October 27, 2021 case management conference, **Special Master Vanaskie directed ZHP to "report to your counterparts in China that the Court has ordered that the deposition be taken by December 15th so that they understand that there is a deadline in place and hopefully this deadline can be accommodated**." (10/27/2021 Tr. 6:17-20 (emphasis added)). As discussed below, ZHP failed to disclose to the Chinese government that the travel was required to attend the Court ordered deposition despite being ordered to do so. On November 22, 2021, ZHP advised the Court that it learned on November 11, 2021 that Mr. Chen would not be produced for his deposition. (ECF 1766, p. 3-4). Thus, ZHP inexplicably waited eleven days to notify Plaintiffs despite the imminent deadline. (12/01/2021 Tr. 5:1-6:8). In light of this history, **Special Master Vanaskie concluded, "I do believe that you [(Plaintiffs)] should be able to move for sanctions."** (*Id.* at 8:6 (emphasis added)).

During this time period, Plaintiffs also faced ZHP's stiff resistance to the production of obviously relevant documents including: (1) the custodial file of Baohua Chen's chief of staff, Xiaofang (Maggie) Kong, who started at ZHP in 2017, and (2) the report investigating the contamination of irbesartan with a nitrosamine, which was discussed in the July 27, 2017 email by Jinsheng Lin, Ph.D. Plaintiffs first raised these requests with the Court on April 27, 2021. (ECF 1189, p. 15-17, 21-22, 24, 26). On May 11, 2021, the Court ordered the production of the report investigating the contamination of irbesartan with a nitrosamine. (ECF 1233). The Court also ordered the production of Maggie Kong's custodial file. (5/12/2021 Tr. 32:15-33:1). During the June 16, 2021 status conference, ZHP asked the Court to extend its deadline for producing Baohua Chen's and Xiaofang (Maggie) Kong's custodial files to July 12, 2021. (6/16/2021 Tr. 14:19-15-24). ZHP still failed to comply, and on July 23, 2021, Plaintiffs filed a motion to compel ZHP's compliance with ECF 1233 as well as the Court's May 12, 2021 order. (ECF 1405). On August 13, 2021, ZHP opposed the motion. (ECF 1485). During oral argument, after the Court again ordered ZHP to produce the custodial file of Maggie Kong, ZHP announced to the Court that it would not comply with the Order due to the intervening passage of China's new Data Security Law. (9/10/2021 Tr. 59:10-61:20; ECF 1550, p. 20-21). **Not surprisingly, Special Master Vanaskie was "disappointed" that ZHP waited until after he issued an order to produce the custodial file to raise this issue.** (9/10/2021 Tr. 62:15 (emphasis added)). On

November 12, 2021, the Court issued yet another Order requiring production of Maggie Kong's custodial file and the Irbesartan report, by November 22, 2021. (SMO 54, ECF 1753). ZHP announced that it would not comply on the day of the deadline. (ECF 1766, p. 4-6). ZHP reaffirmed its position at the December 1, 2021 case management conference. (12/01/2021 Tr. 14:13-15:1).

In the face of this wall of obstruction and violations of Court Orders, Plaintiffs filed their motion for Rule 37 sanctions on December 30, 2021. (ECF 1838). ZHP filed its opposition on February 2, 2022. (ECF 1900). Plaintiffs replied on February 18, 2022. (ECF 1921). On February 28, 2022, ZHP filed a sur-reply. (ECF 1942-2), (ECF 1951).

During a hearing on September 8, 2022 addressing Plaintiffs' ongoing efforts to obtain ordered discovery, ZHP asserted that it had produced the ordered documents, but the Special Master required ZHP to file a certification demonstrating its compliance. (9/8/2022 Tr. 25:22-60:16, 38:5-39:9). The Parties subsequently met and conferred on the issue, and on October 18, 2022, ZHP produced a mere 225 more documents from Baohua Chen's and Maggie Kong's custodial files. Three days later, ZHP's defense counsel sent a conclusory certification to Plaintiffs claiming it had complied, and did not submit the certification to the Court. (ZHP Br., Ex. 1). The certification was not helpful and proved nothing, containing conclusory statements, failing to say anything about what was done or establish why ESI Protocol compliant documents were not produced (e.g. "ZHP02710347 was located

during ZHP's collection of documents only in hard copy, and was scanned to PDF for production…An electronic version was not located.") (ZHP Br., Ex. 1, at paragraphs 8-10), and woefully unexplained references to 544 pages of bates ranges attached to the certification. Despite the Special Master's instruction that "the record should reflect" any certification, ZHP's counsel declined to file the certification, likely recognizing that it was inadequate and would elicit further searching questions from the Special Master. ZHP cannot rely on the inadequate, unfiled Certification at this late date, nor does the Certification provide any substantive details to establish the credibility of ZHP's broad, self-serving conclusions of adequacy.

On October 13, 2022, without leave of Court, and after all briefing and argument was completed on the Baohua Chen deposition issue, ZHP filed a conclusory declaration from a purported expert on Chinese law, Jacques deLisle. (ECF 2175-2). The Special Master struck the declaration on May 4, 2023. (ECF 2371). ZHP never objected to or moved to vacate that order, so it is final. Fed. R. Civ. Proc. 53(f)(2), (5). Despite this, ZHP cynically relies heavily on the stricken Declaration here, which demonstrates a lack of regard for the Special Master's decision and should be disregarded.

On May 10, 2024, the Special Master granted Plaintiffs' motion for sanctions. (SMO 98, ECF 2712). In accordance with that order, Plaintiffs filed their proposed adverse findings of fact seven days later and their request for attorneys' fees, costs, and monetary sanctions another seven days later. (ECF 2721, 2731). On May 31,

2024, ZHP filed its responses to Plaintiffs' proposed adverse findings of fact and request for attorneys' fees, costs, and monetary sanctions, with no substantive objection to Plaintiffs' request for attorneys' fees or costs. (ECF 2736, 2737, at 9-11). ZHP filed its motion to reverse SMO 98 on the same day. (ECF 2738). The Special Master has scheduled oral argument regarding the adverse findings of fact, attorneys' fees and costs, and monetary sanctions, for June 25, 2024. (ECF 2747).

STATEMENT OF FACTS

A. Baohua Chen Is the Linchpin of the ZHP Organization and Its Contaminated Valsartan.

SMO 98 correctly recites Baohua Chen's central role in the ZHP organization including the development, manufacture, sale, and recall of its contaminated valsartan. (SMO 98, at 2-4). Baohua Chen is the CEO of ZHP and Shanghai Syncores. (ZHP00076700, Ex. 1;[3] ZHP00076708, Ex. 2). Syncores is ZHP's wholly-owned research unit that in 2011 developed the ill-fated zinc chloride manufacturing process that resulted in contamination of valsartan with NDMA. An organization chart states that, "[a]ll the VP or directors are reported to Baohua Chen [d]irectly." (ZHP00076709, Ex. 2).

Baohua Chen had direct involvement with valsartan. According to ZHP's Drug Master File (DMF) for valsartan, which was filed with the FDA, Mr. Chen was

[3] Unless otherwise noted, all exhibits are attached to the Certification of Adam M. Slater in Support of Plaintiffs' Motion for Rule 37 Sanctions Against ZHP.

in charge of the quality department whose failings are at the heart of this litigation: **"The Quality unit, which is divided into QA, QC and QR, is lead [sic] by the General Manager *independent* from manufacturing and sales departments, covering all functions and actions necessary to provide adequate confidence that the finished product manufactured by the company will be perform the intended purpose with regard to safety, purity and effectiveness."** (ZHP01662359 (emphasis added), Ex. 3). **Mr. Chen is listed as the General Manager and Chairman, a "Chemical Engineer," who "graduated from Zhejiang University of Technology in 1983 and worked in Zhejiang Haimen Pharmaceutical Factory from 1983 to 1989. …. He has wide experience in the product development and quality management of bulk drugs."** (ZHP01662344-44 (emphasis added), Ex. 3; *see also* ZHP01633861, 77, Ex. 4; ZHP01458558, 59, Ex. 5).[4] **Baohua Chen has a Master of Science in Chemical Engineering.** (ZHP00004937 (emphasis added), Ex. 6). ZHP's valsartan DMF also states that as **the "General Manager," to whom all vice presidents and directors report he effectively leads all of ZHP's departments and is responsible for coordinating**

[4] A DMF is the regulatory filing that an API manufacturer files with the FDA in order to allow finished dose manufacturers to incorporate its API into their finished dose form of a generic medication. *See* FDA, *Drug Master Files (DMFs)*, https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs. This Court should give significant weight to the claims made in such a filing.

and synthesizing their disparate activities. He managed 3,800 employees as of May 2014. (ZHP00004937, Ex. 6).

During FDA inspections, Baohua Chen told the FDA that he "**has the ultimate authority at the firm and takes full responsibility for the company's operations**." (PRINSTON00083647 (emphasis added), Ex. 7).[5] He participated in at least seven FDA inspections during the relevant time period, in August 2013, May 2014, March 2015, November 2016, June 2017, January 2018, and June 2019. At the August 2013 inspection, the Vice General Manager of Quality Assurance said that he reported directly to Baohua Chen. (PRINSTONO0083002, Ex. 8). After that inspection, Baohua Chen "promised to correct/evaluate all discussion items and to expand the corrections to any related issues." (PRINSTON00083010, Ex. 8). The March 2015 inspection report identified Baohua Chen as the "most responsible person." (PRINSTON00083028, 31, Ex. 9). The May 2014, November 2016, and January 2018 inspection reports state that all FDA correspondence should be addressed to Baohua Chen. (PRINSTON00074128, Ex. 10; PRINSTON00081551, Ex. 11; PRINSTON00081574, Ex. 12).

In the 2010 contract between ZHP and Shanghai Syncores to develop the Valsartan zinc chloride manufacturing process, Baohua Chen is also listed as

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[5] The document clearly states that "[a]t the close-out meeting, the firm was represented by Baohua Chen." (PRINSTON00083644, Ex. 7). ZHP's repeated efforts to paint Mr. Chen as a know-nothing figurehead are as cynical as they are belied by the documents.

Shanghai Syncores's legal representative. (ZHP0000222, an English translation, Ex. 13). **During a November 1, 2013 meeting regarding the optimization of ZHP's API manufacturing processes through the new zinc chloride process, Baohua Chen defined the priority of the project as the cost of Valsartan depending on the manufacturing process used**. (ZHP02579748 (emphasis added), Ex. 14). This is the core ZHP motive leading to the contamination—ZHP decreased cost and increased yield for marketing leverage at the expense of purity and safety. **Baohua Chen's focus on reducing the cost to manufacture valsartan and the price that could be charged to control market share based on the reduced cost, micromanaged the price for its Valsartan API, even at the level of its U.S. subsidiaries**. (SOLCO00012089, Ex. 15 (stating that **"Mr. Chen is not satisfied with our share [of Valsartan- HCTZ] and wants us to target 40%!"** (emphasis added));[6] SOLCO00189499, Ex. 16 ("Mr. Chen wants to know the update March sale since the last month went to very bad. Could you give me some rough number based on your estimate?" (sic)); SOLCO00025179, Ex. 17; SOLCO00033301, Ex. 18; SOLCO00181380, Ex. 19; SOLCO00180393, Ex. 20). **Demonstrating the practical significance of the strategy spearheaded by Baohua Chen, ZHP told**

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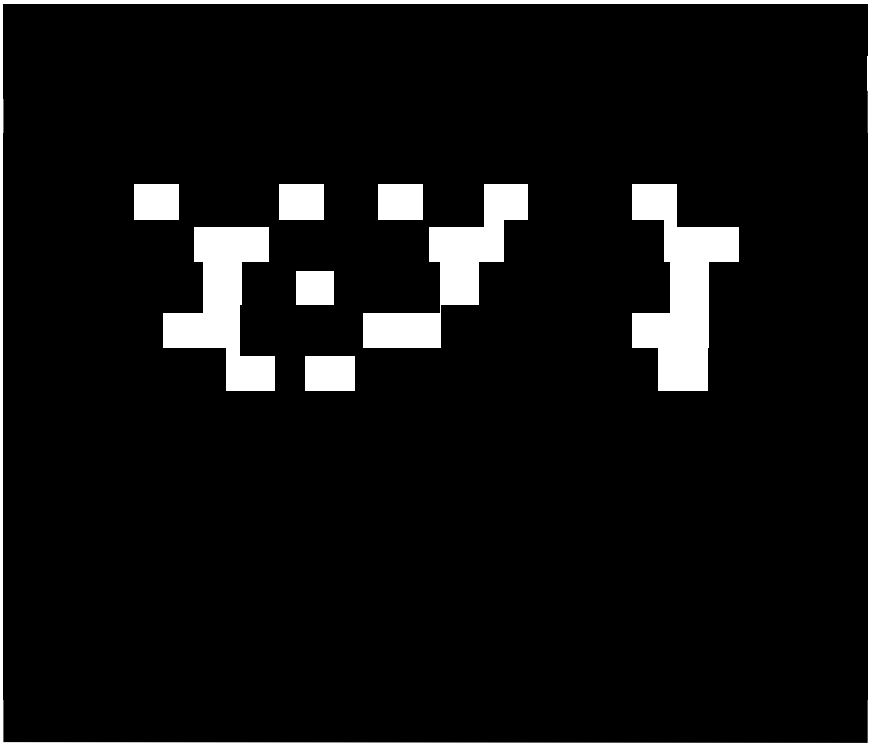
[6] This document shows Mr. Chen decided what market share to target for valsartan at ZHP and even its U.S. subsidiaries, and only Mr. Chen knows how he established the targets, and his assessment of the importance of the manufacturing processes to attain those targets - and consequent failure to ensure that ZHP stopped manufacturing with processes creating genotoxic nitrosamines including NDMA and NDEA.

the FDA investigator that it changed to the contaminating zinc chloride manufacturing process in order to lower the cost of its valsartan, and ZHP was able to dominate the world market as a result. (PRINSTON00162373, Ex. 21).

Baohua Chen also led ZHP's recall of Valsartan. ZHP's "Protocol of Valsartan API Recall (Foreign grade)" lists Baohua Chen as the first member of the "Recall Group." (ZHP00494048, Ex. 22). Baohua Chen even wrote directly to the European Directorate for the Quality of Medicines (EDQM) regarding ZHP's corrective and preventative actions (CAPAs) to correct the massive systemic cGMP deficiencies that allowed the nitrosamine contamination to occur, requesting permission to again sell valsartan. The letter is detailed, substantive, acknowledges the many cGMP violations including the inadequate risk assessment, and demonstrates Baohua Chen's central knowledge and involvement, including:



(ZHP01423197 (emphasis added), Ex. 23). Baohua Chen had met directly with ZHP's consultants regarding how to respond to the EDQM's September 2018 inspection. (ZHP00292153, Ex. 24). That inspection largely focused on the contamination of ZHP's valsartan and found nine major cGMP deviations and eight minor ones. (ZHP00292149, Ex. 24). During a May 6, 2019 meeting, Baohua Chen complained about the EDQM's requirements, stating: "No one can achieve this level. It is impossible for everyone to apply the latest and strictest standards to the past." (ZHP02666849, Ex. 25). **At the same meeting, Baohua Chen cynically and tellingly directed his subordinates to cease sharing information with Novartis, the ZHP customer who discovered and forced disclosure of the contamination: "Refuse to provide the [investigation] report to Novartis/Sandoz and … stop cooperation in the future.**" (*Id.* (emphasis added)) ZHP 30(b)(6) witness Min Li testified that after the June 2018 disclosure of the contamination to the FDA and other regulatory authorities, which only occurred after Novartis discovered the contamination and forced ZHP to disclose it (see below), **Baohua Chen took**

control of the crisis and made it a "top priority of the company," organizing numerous meetings with people including top management. (4/22/2021 Tr. of Min Li Dep. 581:14-582:5 (emphasis added), Ex. 40).

Significantly, before the recall, Baohua Chen paid close attention to the communications with Novartis that ultimately forced ZHP to disclose the nitrosamine contamination of its Valsartan. (ZHP00667853, Ex. 31). After the recall, he became Novartis' primary contact. (*See* PRINSTON00468994, Ex. 32; ZHP02471924, Ex. 33; ZHP02490581, Ex. 34). Mr. Chen's involvement was not distant and supervisory—he was the engaged leader of ZHP's work on this matter.

Shortly after the disclosure of the nitrosamine contamination, Baohua Chen met with Chinese government officials about the contamination. (TEVA-MDL2875-00611842, Ex. 26). Baohua Chen also handled commercial customer complaints regarding the contamination, demonstrating how wide his direct involvement stretched. One customer summarized its meeting with Baohua Chen as follows: **"Do appreciate Mr. Chen will express Huahai's regret for what happened and the willingness to listen and make a step towards Menarini's claims for damage."** (ZHP01224767 (emphasis added) (an earlier email in the chain stating that "*[a]fter the big nitrosamines 'earthquake',* we do believe it is necessary and important to have a top level meeting between Huahai and Menarini. *It is also our CEO Mr. Chen's idea to particularly pay you a visit to strengthen the relationship.*" (emphasis added)), Ex. 27). Baohua Chen was also the main point of contact for another

defendant in this case after the recall—Teva. (*See* TEVA-MDL2875-00662718, Ex. 28; TEVA-MDL2875-00370081, Ex. 29; ZHP01761094, Ex. 30).

Jun Du, the head of ZHP's U.S. subsidiaries, testified that his title as ZHP's Executive Vice President was temporary and for the convenience of Baohua Chen: "Those were merely interim assignments. **Whenever Baohua Chen as the general manager was unavailable, someone was needed for the coordination.**" (5/27/2021 Tr. Jun Du Dep. 34:5-8 (emphasis added), Ex. 39). This further demonstrates Mr. Chen's central role. Yet another example of Baohua Chen's active role, when ZHP developed the sartan intermediate Bro-OTBN, subordinates were required to "[r]eport to President Mr. Chen routinely (e.g. every two weeks) to let him follow Bro-OTBN development continuously, [as] this will help Mr. Chen to make quick and clear decision." (ZHP02385482, Ex. 35).

Hai Wang, the Vice President of Prinston and President of Solco, testified that Baohua Chen regularly visited the United States to oversee the ZHP marketing operations and pricing in the US through its wholly owned subsidiaries Huahai US, Prinston, and Solco. (3/11/2021 Tr. of Hai Wang Dep. 542:18-43:5, Ex. 43). The Facebook page of PrinJohnson, an intermediate holding company between Huahai US and Prinston, which in turn owns ZHP's U.S. distribution subsidiary Solco, focuses on Baohua Chen's involvement in these operations, including pictures of Mr. Chen in New Jersey. (Photo from PrinJohnson's Facebook Page, Ex. 42). (Photo from PrinJohnson's Facebook Page, Ex. 42).

SMO 98 correctly established that Baohua Chen was involved at every point in the valsartan life cycle, and the importance of his deposition. The failure to produce him for his court ordered deposition is enough, standing alone, to support the sanctions assessed in SMO 98.

B. ZHP Is Still in Violation of Special Master Order 54.

Maggie Kong is the chief of staff for Baohua Chen, whose custodial file only contained 326 documents when first produced, the earliest of which was dated January 24, 2018. (Ex. 36). ZHP subsequently amended its production to add Baohua Chen as a duplicate custodian on an additional 306 documents, none of which predated January 24, 2018. And then in anticipation of serving the October 22, 2022 declaration, ZHP added 12 documents to Baohua Chen's file, again none before 2018 and none during the last week of May 2018 or the first two weeks of June 2018. Of course, many of the key events, including the July 27, 2017 email, and a string of complaints from ZHP API customers about unidentified peaks on gas chromatography that included the peak for the NDMA impurity, pre-dated 2018. (Qiangming Li 4/14/2021 Dep. Tr. 130:7-170:11, 177:22-199:20, 204:11-214:17, Ex. 55; 290:16-318:10, 254:22-290:4, 343:21-372:9, 386:17-466:17, Ex. 56). Even after its irbesartan-specific productions, Baohua Chen's file only contains 765 documents and still none from before January 24, 2018, and only 68 before June 15, 2018, with 10 being useless slip sheets stating "Withheld – Other Products." Crucially, **his file only contains two irrelevant documents dated between May**

24, 2018, and June 15, 2018, which is the crucial time frame in which Novartis first discovered the NDMA contamination and told ZHP, which attempted to deflect the issue, and Novartis insisted that ZHP had to disclose it to the FDA. (see below).[7]

At the time of Plaintiffs' initial Rule 37 motion, ZHP had not produced any part of Maggie Kong's custodial file. ZHP began to slowly produce parts of that file on February 2, 2022. The production is obviously inadequate. This begins with **the same black hole as with Baohua Chen's file, no documents between May 21, 2018, and June 15, 2018, despite the interaction with Novartis during that time period.** As of the date of defense counsel Richard Bernardo's October 21, 2022 certification, her file had a scant 1,240 documents. Only 65 of those documents pre-dated Novartis' discovery of the nitrosamine contamination, and 33 of those documents are unhelpful slip sheets stating, "Withheld – Other Documents." When the irbesartan-specific productions are included, her file has 158 documents before June 15, 2018, with 36 of those being worthless slip sheets stating "Withheld – Other Documents." And her custodial file still has a gap between May 24, 2018, and June 15, 2018.[8]

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[7] The only two documents in Baohua Chen's file during the last week of May are an email and the attached PowerPoint Presentation from May 24, 2018, regarding Prinston's manufacturing facility in Charlotte, North Carolina.

[8] Her only two documents during the last week of May 2018 are the same ones as in Baohua Chen's file.

The significance of the overlapping gaps in the Baohua Chen and Maggie Kong custodial files in May-June 2018 is glaring when one looks at what was happening during that time frame.[9] On May 22, 2018, Novartis, which had been provided valsartan API by ZHP to evaluate with the plan to purchase and use that API to manufacture valsartan finished dose pills, notified ZHP that based on its routine residual solvent testing via gas chromatography, [redacted]

(ZHP00405021, Ex. 57). ZHP responded, "Our QC will check and comment soon." (ZHP00359816, Ex. 58). Novartis replied, "Is there any information on what these extra peaks are?" (ZHP00359815). On May 22, 2018, ZHP dismissively provided explanations for three of the peaks shown on the gas chromatography and asked, "Please kindly let us know if you have any further questions." (ZHP00359813-14). Novartis persisted, "Have you any possibility of performing identification work on the unidentified peaks?" (ZHP00359813). On May 24, 2018, ZHP committed to "proceeding the investigation on the unidentified peaks." (ZHP00359810-11). Novartis requested a call the next day. (ZHP00359809-10). On May 25, 2018,

[9] ZHP quibbles with the number of documents they produced; however, the point is the overall inadequacy of the volume of documents produced, and the significant material gaps when none were produced, including during the crucial back and forth with Novartis which required ZHP to cease its cover up. And ZHP's reliance on its unfiled conclusory certification of counsel that was never sent by ZHP to the Special Master, that provides no substantive basis to find that ZHP's production was adequate, is completely unavailing.

Novartis and ZHP had a call, and per Novartis' request, ZHP committed to providing Novartis with a formal report by May 31, 2018. (ZHP00359808). Four days later, Novartis asked, "Is there an update on how the identification work is going at [ZHP]?" (ZHP00359807). ZHP wrote that it was "on-going" and would be provided by June 1, 2018. (*Id.*). Novartis then asked for the report by May 31, 2018. (ZHP00359806-07). ZHP then sent the report to Novartis. (ZHP00359805). **That report falsely concluded, "The product quality is less likely to be impacted**." (ZHP01871002 (emphasis added), Ex. 59). The next day, Novartis asked for ZHP to evaluate 17 lots of valsartan to confirm they "are within the limits defined by the report." (ZHP00359803-4, Ex. 58). **On June 4, 2018, ZHP sent a report to Novartis, again falsely concluding, "The product quality is less likely to be impacted**." (ZHP00359802; ZHP000021465, Ex. 60).

Novartis, as a responsible finished dose manufacturer, persisted in questioning the unidentified peaks in ZHP's valsartan rather than accepting ZHP's deflections. (ZHP00359801, Ex. 58).[10] On June 5, 2018, Novartis informed ZHP that it had hired a third-party lab to test three batches of ZHP's valsartan and found NDMA. (ZHP00359796-800). Dr. Li, who reported directly to Mr. Chen, was a recipient of

[10] As already noted, Baohua Chen paid close attention to the communications with Novartis that ultimately forced ZHP to disclose the nitrosamine contamination of its Valsartan, and after the recall, he became Novartis' primary contact. (*See* ZHP00667853, Ex. 31; PRINSTON00468994, Ex. 32; ZHP02471924, Ex. 33; ZHP02490581, Ex. 34).

this email. (*Id.*). The next day, Novartis asked to schedule a call. (ZHP01390020, Ex. 61). Instead of having the call with Novartis, ZHP feigned ignorance and wrote that "I have checked with Dr. Li's team, actually it will take some time to do study on the potential Nitrosodimethylamine impurity," so "may we suggest to postpone the TC to next week once we have more update and comments?" (ZHP01390019). As stated above, Dr. Li, who reported directly to Baohua Chen, was the head of CEMAT, where Jinsheng Lin was in charge of identifying process impurities and their root causes—and he reported directly to Dr. Li.

On June 7, 2018, Novartis sent another email correctly describing the root cause for the creation of NDMA: "DMF is known to be subject to hydrolysis, releasing dimethylamine and formic acid, in particular at elevated temperature in the presence of acids or bases," which then reacts with sodium nitrite to form NDMA. (ZHP01390017-18). Dr. Li and Peng Dong, another recipient of the July 27, 2017 email, both received this email from Novartis. Without knowing it, Novartis was simply repeating the key part of Jinsheng Lin's July 27, 2017 email to ZHP detailing the NDMA known to be in valsartan and the root cause of the contamination. Yet, ZHP was still trying to cover up the contamination, most likely directed by Baohua Chen, to whom Dr. Li reported directly.[11]

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[11] ZHP says it "only located a PDF version of the document" in explaining away its failure to produce the native version of the July 27, 2017 email with its metadata, but never explained how this happened, especially since it was sent to more than 10 people. (ZHP Br. 13). This is because there is no credible explanation.

[redacted]

The second category of inadequate document production concerns the irbesartan investigation discussed in Jinsheng Lin, Ph.D.'s July 27, 2017 email. After the email was sent, CEMAT further investigated the impurity issue identified in the email, and a report was written over the course of time. Jinsheng Lin sent Min Li an email on December 22, 2018, attaching an Excel file summary of all the projects being undertaken by CEMAT with a long report review cycle. (Min Li 4/20/2021 Dep. 125:19-126:6, 127:20-128:7, Ex. 48). Within the Excel file attachment at tab 1.3, row 54, the story of that report is presented, confirming that the investigation of the Irbesartan impurity was performed and the report of that investigation was compiled through the end of 2017. (*Id.* at 128:11-138:17). Then in early 2018, the

report was sent to Min Li for approval. (*Id.* at 136:5-10, 138:13:18-139:17). The January 2018 update indicated that "the research report was completed pending review." (*Id.* at 138:18-21). Finally, in April 2018, the progress update stated: **"After discussing with Mr. Li, as the project involves an impurity that is sensitive so no research report will be issued and no further updates will be made."** (*Id* at 139:2-7) (emphasis added)).

ZHP produced a single copy of this investigation report after the Court ordered it to produce all copies. Like the July 27, 2017 email, ZHP has not produced a native version of this document with the related metadata, in violation of the ESI protocol. The report focuses in large part on the root cause for the nitrosamine impurity—reaction with nitrous acid, the same root cause identified in the July 27, 2017 email. (ZHP02710348, 50, 51, an English translation (emphasis added), followed by the original document, Ex. 49). The failure to produce all drafts, and all intact metadata for all versions, was an obviously material violation of the Court's orders, especially in light of Min Li's directive to bury the report due to the discussion of the "sensitive impurity." This is a clear and unexplained violation of the Order compelling production and the ESI Protocol, as the document was clearly created using a computer. The obvious violations have never been explained, ZHP merely stating, "ZHP was only able to find the document in PDF format." (ZHP Br. 26 (citing Bernardo Cert. at ¶ 9)). ZHP's explanations for the material gaps in the production are completely inadequate.

ARGUMENT

I.

ZHP'S FAILURE TO COMPLY WITH MULTIPLE COURT ORDERS WARRANTS SANCTIONS

SMO 98's sanctions are measured and appropriate. The Special Master correctly recognized the need to meet ZHP's obstruction, most notably the failure to produce its top executive for a court ordered deposition, and the failure to produce key documents in violation of multiple court orders. Decisive sanctions are the only means to avoid further discovery obstruction and avoid setting a dangerous precedent in this litigation, and beyond, that would further incentivize foreign manufacturers to hide behind blocking statutes.

A. ZHP Acted in Bad Faith in Failing to Produce Baohua Chen for His Deposition.

The Special Master correctly held that Rule 37 sanctions are warranted here:

> ZHP asserts that a court may not sanction a party for its failure to comply with discovery orders when the failure is premised on a foreign law prohibiting disclosure. However, in the same case on which ZHP relies for this assertion, *In re Westinghouse Electric Corp. Uranium Contracts Litig.*, the court recognized the power of a court to sanction a party for its failure to comply with discovery orders despite the foreign illegality, finding "it to be implicit in *Société* that foreign illegality does not necessarily prevent a local court from imposing sanctions when, due to the threat of prosecution in a foreign country, a party fails to comply with a valid discovery order." 563 F.2d 992, 997 (10th Cir. 1977).

(SMO 98, at 14-15). This is fully consistent with Judge Kugler's Chinese state secret decision: "Any expectation that a PRC law will successfully shield discovery in a U.S. litigation needs a tempering of realism. That is, PRC defendants must know from the outset they *risk serious consequences if and when they fail to obey a U.S. court's order to compel discovery*. These consequences arise from the clearly enumerated authority under Rule 37, which U.S courts wield as needed." (*Id.* at 7).

ZHP's arguments are disingenuous at best, for example claiming ZHP "acted in the best of faith" and was more diligent than the defendant in *Westinghouse.* This throwaway self-serving pat on the back is oblivious to the concerted efforts taken by the defendant in *Westinghouse* to get the Canadian government and Canadian Supreme Court to allow the production there. (ZHP Br. 16-18). The history makes this clear. This Court originally ordered Baohua Chen's deposition on December 31, 2020, and the Parties scheduled his deposition for May 31, 2021. (ECF 704). However, Sihan Lu's unavailing declaration, which the Special Master correctly found to be unpersuasive, admits that **ZHP first contacted the Taizhou Federation of Industry and Commerce to obtain permission for the deposition in early June 2021, after the deposition was originally scheduled to take place**. (ECF 1900-1 (emphasis added)). This delay is inexcusable and is clear bad faith. ZHP ignores its obviously inadequate efforts.

The declaration further illustrates the inadequacy of ZHP's efforts, indicating that Sihan Lu was previously unaware that she would need to submit an application

for Baohua Chen to leave mainland China. (*Id.*). Instead, she called the Taizhou Federation of Industry and Commerce (where Baohua Chen is the Chair, as stated on page two of the application) and was informed she needed to submit a form, which she did not even have, so she needed to go to the Federation and obtain it. (*Id.*). Thus, despite Mr. Chen's role as Chair of the relevant government entity, ZHP tasked an inexperienced and uninformed administrator with this important application. This is superimposed on the fact that Baohua Chen has traveled out of China on ZHP business, including to New Jersey, when it has served ZHP's interests.

The application is also materially incomplete. (Ex. 2 to ECF 1900-1).[12] The first page does not provide the "Country/Region," and the third page contains an astonishingly generic explanation of the "Reasons for application and period." It simply states, "Due to requirements of the case, it is necessary to go abroad (exit border) to deal with the company's overseas litigation matters." The fourth page does not include the "Opinions from the leader in charge," the place to include a statement from Baohua Chen himself, as the CEO and General Manager. The Special Master pointedly observed, "**The application does not mention that Mr. Chen was ordered by a federal court in the United States to appear for a deposition and**

[12] ZHP has not filed the exhibits to Sihan Lu's declaration on the docket, and Plaintiffs were only able to receive the exhibits after agreeing to limit their disclosure in accordance with the terms of the Court's prior Chinese state secret order. If the Court does not have access to the exhibits, ZHP should provide them to the Court or Plaintiffs can.

does not list the importance of the deposition that the court order reflected. …. Nor did ZHP attach to the application a copy of the Special Master Order ordering Mr. Chen to be deposed." (SMO 98, at 19 (emphasis added)). This failure violated the Special Master's explicit direction that ZHP inform the Chinese government that the travel was necessary to comply with a United States Court Order. (10/27/2021 Tr. 6:17-20). "**ZHP failed to adhere to the Special Master's instruction to ZHP to stress the importance of the deposition**." (SMO 98, at 21 (emphasis added)). The Special Master did not rule that ZHP failed to "take every conceivable step for persuading the Chinese government to grant Mr. Chen's visa permit." (ZHP Br. 19). Rather, the Special Master found, as clearly demonstrated by the record that "ZHP has not taken all reasonable steps to comply with this Court's orders throughout this proceeding," and displayed a "lack of forthrightness." (SMO 98, at 19-21).

After being questioned about these glaring deficiencies during oral argument of the Rule 37 motion for sanctions, ZHP hired Jacques deLisle as a purported expert to try to fill in the blanks. As explained above, the Court struck that declaration, and ZHP never moved to reverse that decision. ZHP falsely suggests that the declaration was requested. In fact, the Special Master did not request or authorize it, but rather commented on the complete lack of foundation for the arguments that were being made during the argument. No invitation was extended, let alone any Order filed, allowing ZHP to supplement the record following the argument. The late filed

declaration was correctly precluded, as a similar filing by Mr. Delisle was rejected by another Court, *See Stross v. NetEase*, No. CV 20-00861, 2020 WL 5802419, at *1 (C.D. Cal. Aug. 20, 2020), and it cannot be considered.[13]

ZHP also ignores Exhibit 27 to Plaintiffs' motion, which shows that Baohua Chen left China in October 2019 to meet with valsartan customers who expected "Mr. Chen [to] express Huahai's regret for what happened and the willingness to listen and make a step towards [redressing the customer's] claims for damage." (ZHP01224767, 1224770, Ex. 27). This is clear evidence that the blocking statute is applied in a biased manner to frustrate the United States Courts, while Mr. Chen has been permitted to travel for the commercial purposes of ZHP. The Special Master correctly found: "By failing to take all reasonable efforts to make Mr. Chen available for his deposition, ZHP has done the equivalent of making no effort to comply with the Court's discovery orders. Thus, ZHP's conduct is sanctionable under Rule 37." (SMO 98, at 20-21). The record clearly supports this conclusion.

ZHP also questions who the third-party would be to help it obtain approval for Baohua Chen's travel for the deposition; however, ZHP admits that such organizations are available. (ZHP Br. 22-23).

[13] The declaration is not of any moment on a substantive basis anyway. It is nothing more than an ipse dixit conclusory opinion based on speculative, unexplained assumptions, written with a series of hedges about what possibly occurred.

ZHP also recycles its argument that Plaintiffs did not resort to the Hague Convention to secure Baohua Chen's deposition. (ZHP Br. 18-19). The Special Master properly rejected this argument: "ZHP's reliance on this argument is misplaced, as courts have held that a party is not required to resort to the Hague Convention protocols before utilizing general discovery rules. *Société Nationale Industrielle Aerospatiale v. U.S. Dist. Court for Southern Dist. of Iowa*, 482 U.S. 522, 543 (1987) (declining to adopt petitioner's invitation to establish new rule that 'would require first resort to Convention procedures whenever discovery is sought from a foreign litigant.')…. The court in *Inventus Power*, 339 F.R.D. at 503, reported that in more than 30 years under the Consular Convention and 13 years under the Hague Convention, China has granted permission for a deposition on only one occasion.' Given the inability of ZHP to obtain permission for Mr. Chen to travel for his deposition, it is a virtual certainty that China would have denied permission for Mr. Chen to be deposed under the Hague Convention." (SMO 98, 15, 16).

B. ZHP Repeatedly Fought the Production of Xiaofang (Maggie) Kong's Custodial File and All Versions of the Irbesartan Investigation Report with Metadata in Bad Faith, and Those Productions Are Still Incomplete.

ZHP attempts to undercut the Special Master's decision regarding its document production by pointing to a self-serving, conclusory certification from its attorney that was never made part of the record—and does not change the fact that ZHP has not fully complied with SMO 54. Notably, ZHP's inadequate effort to comply with SMO 54 only came after Plaintiffs filed their motion for Rule 37

sanctions, and ZHP never submitted the certification to the Special Master. Moreover, to the extent ZHP belatedly produced a small number of the ordered documents, despite its repeated assertions that there was nothing else, this further illustrates ZHP's bad faith when it repeatedly stated that it had produced everything, and does not fill the material gaps that remain.

To be clear, the certification was never part of the record before the Special Master because ZHP never submitted it. Moreover, the certification simply repeats ZHP's prior unsubstantiated and later proven false claims from the September 8, 2022 oral argument that it had produced everything required pursuant to SMO 54. (*See* 9/8/2022 Tr. 37:10-39:2). We know that the September 8, 2022 statements were false because ZHP produced additional documents required by SMO 54 three days before signing the certification at issue. Moreover, those documents did not cure the material gaps in Maggie Kong's custodial production or add any versions of the irbesartan investigation report relating to the July 27, 2017 email.[14] Nor does the certification acknowledge or provide any explanation for those missing documents.

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[14] ZHP cites the Special Master discussing Plaintiffs' initial Rule 37 motion, which was filed before ZHP decided to comply with parts of SMO 54, to claims the Special Master based his decision on four different categories of missing documents. (ZHP Br. 25 (citing SMO 98, at 5)). But ZHP's arguments do not address the Special Master's basis for the sanctions in addition to the failure to comply with the Order to produce Baohua Chen for his deposition: the incomplete Xiaofang (Maggie) Kong custodial file and the missing irbesartan investigation reports and metadata. (ZHP Br. 26), as well as the failure to produce the required native version of the July 27, 2017 email with its metadata. These are the documents at issue on this motion, and ZHP does nothing more than shrug at its failure to do as required.

ZHP attempts to create the illusion of compliance by referencing the few documents it did produce. The Special Master correctly commented on ZHP's gamesmanship, for example where it delayed until the Data Security Law was passed, then tried to hide behind it: "While such reliance may be skillful from ZHP's perspective, it is inconsistent with ZHP's duty to comply with American discovery while doing business in the United States." (SMO 98, at 24). This is quite telling, and further illustrates ZHP's bad faith.

Moreover, the numbers of documents produced remain small, especially when noting the gaps, so these arguments should be rejected. As explained above, by the date of the certification, Ms. Kong's custodial file had only 65 documents from before June 15, 2018, and 33 of those documents are slip sheets stating "Withheld – Other Documents." The 33 slip sheets are useless to Plaintiffs and the referenced documents irrelevant to Plaintiffs' claims entirely. More important, Ms. Kong's and Mr. Chen's respective custodial files contain no documents dated during the crucial final week of May 2018 and the first two weeks of June 2018, the key period of time related to Novartis' discovery of NDMA in ZHP's valsartan. (*See* above). Both custodial files also lack documents from 2017 or earlier. Both of these gaps persist even when including the subsequent irbesartan-specific productions.

The failure to produce all drafts and metadata for the irbesartan investigation report is also important. As it stands, ZHP has still only produced a single version of the report, which was unquestionably written on a computer and should have been

produced with all of its related drafts, and the metadata for each, as ordered. With the metadata and drafts (to see what was stated but later changed or deleted), Plaintiffs would have the full picture, but that has been hidden by ZHP.

The certification of ZHP's attorney does not provide any explanation for these gaps either. Just as ZHP had been withholding documents before the September 8, 2022 oral argument, it is reasonable to infer that more documents exist, but ZHP has decided to withhold them. ZHP's strategy to give over discovery in piecemeal fashion only when pressured, despite the fact that the documents should have been produced from the very beginning is exactly the type of bad faith Rule 37 is meant to address.

SMO 98 is more than adequately supported by the record. ZHP's effort to elevate inadequate, conclusory arguments in order to create the illusion of compliance falls apart when scrutinized and should be rejected.

II.

THE SPECIAL MASTER'S SANCTIONS ARE APPROPRIATE

The Special Master's analysis is thorough and well-balanced, including application of the six *Poulis* factors. (*Id.* at 26-38). He also rejected Plaintiffs' requested relief of striking and suppressing ZHP and its subsidiaries' Answer and Defenses, deeming the allegations in Plaintiffs' Master Complaints admitted with respect to ZHP and its subsidiaries for all purposes, demonstrating that his evaluation was measured. (*Id.* at 35).

A. The Adverse Findings of Fact Is an Appropriate Sanction.

The Special Master made the determination to impose this sanction based on an extensive record of significant discovery obstruction over the course of years. ZHP's arguments are disingenuous and fail to grapple with the record. The Special Master explained the basis for the adverse findings of fact, in part:

> Notwithstanding the laws of the PRC, the fact remains that ZHP has failed to comply with court ordered discovery and committed sanctionable conduct. **Its failure to provide the native file for the July 27, 2017 email and its absence from the production made from custodial files of key ZHP personnel is especially troubling. The absence of this information and the extensive efforts to preclude Mr. Chen's deposition testimony support an inference that ZHP was aware of the contamination of valsartan long before it was disclosed by a ZHP customer**. Under these circumstances, and utilizing the Restatement approach, it would be proper to sanction ZHP by an adverse inference instruction that the information that Mr. Chen's deposition and the requested documents would have provided would be adverse to ZHP. *See* Restatement (Third) on Foreign Relations, § 442(c).

(SMO 98, at 36-37 (emphasis added)). Plaintiffs' proposed adverse findings of fact are consistent with the ruling, including supporting citations to the Special Master's decision. (ECF 2721-1).

ZHP's motion is premised on a dismissive approach to the Special Master's thorough opinion, and the fanciful assertion that Baohua Chen had nothing to do with anything of significance in this case. However, the Court repeatedly rejected this mischaracterization based on the extensive record. ZHP's refusal to argue based

on the true facts demonstrated in the record relied on and cited at length by the Special Master, is fatal to its motion and is another example of ZHP's bad faith in these discovery disputes.

To be clear, Baohua Chen was a key player, as he was involved in the valsartan development, marketing, and sales, focusing the strategy on reducing cost and increasing market share. (*See, e.g.*, ZHP00076708, Ex. 2). The July 27, 2017 email was sent to two department heads who reported directly to Mr. Chen: Min Li and Lihong Lin who was the head of the regulatory department, as well as other important members of other departments. The email described, "an extremely high GMP risk," and concluded with a plea to action, "[L]eaders please pay attention to this issue." (ZHP 296, Ex. 37). The Leader managing these recipients was Baohua Chen. As Jun Du stated, Baohua Chen's role as General Manager included "coordination" of the various departments within ZHP as well as its subsidiaries. (5/27/2021 Tr. Jun Du Dep. 34:5-8, Ex. 39). It is easy to understand why ZHP chose to violate Court Orders rather than allow its top executive to be confronted with these facts, and the Special Master's decision correctly recognized the inter-connection. ZHP's unsupported assertion that Mr. Chen knew nothing about the email is a conclusion with no foundation, and is directly contradicted by the record. The weak denials and deflections by Mr. Chen's employees certainly do not move the needle in that direction, for example one saying "I don't think Mr. Chen has any time for that," and Jucai Ge's tortured interpretation of the July 27, 2017 email was based on

a purported hearsay discussion with Dr. Lin—which is inadmissible and was completely contrary to the 30(b)(6) testimony of Dr. Lin's boss, Min Li, who confirmed what the email said while testifying for and as ZHP. (ZHP Br. 6, 11-12; Min Li 4/20/2021 Dep. 82:11-12, 87:19-88:7, 88:13-89:18, Ex. 48 (discussing ZHP-295, Ex. 54)).

If they had been produced, the missing drafts of the irbesartan investigation report, with full metadata, would have also been very informative to Plaintiffs. As explained above, that investigation was canceled in April 2018 by Min Li, who reported directly to Mr. Chen, due to the sensitive impurity at issue—a nitrosamine like NDMA. And as detailed above, Baohua Chen's and Maggie Kong's custodial files do not have any documents (with the exception of an irrelevant email and attachment) from the crucial last week of May 2018 and first two weeks of June 2018 when Novartis was discovering the existence of NDMA in ZHP's valsartan, despite ZHP's extensive efforts to convince Novartis there was nothing to be concerned about. ZHP's feigned ignorance of the contamination during this time period was a clear continuation of the cover up so that ZHP could continue to "dominate the world market" for valsartan, as sales continued every day during that back and forth. (PRINSTON00162373, Ex. 21). All of these issues interrelate.

ZHP's own brief inadvertently supports the Special Master's approach: "It is well recognized that '[b]efore drawing an adverse inference, courts typically require some showing, **by circumstantial evidence or otherwise**, of the content of the

destroyed evidence,' as well as a showing that 'a reasonable jury could **infer** that the [missing discovery] contained' the information the jury is instructed to infer." (ZHP Br. 32 (quoting *Emerson v. Wetherill*, No. CIV. 92-4082, 1994 WL 249769, at *3 (E.D. Pa. June 1, 1994)) (emphasis added) (citing *Consol. Aluminum Corp. v. Alcoa*, Inc., 244 F.R.D. 335, 347 n.26 (M.D. La. 2006))).[15] That is exactly what the Special Master did here, and more. (SMO 98, at 35-38). The Court should consequently affirm this sanction.

B. ZHP Is Estopped From Challenging Monetary Sanctions, Which Are Also Appropriate.

ZHP does not challenge the propriety of a court awarding attorneys' fees and costs under Rule 37, so that is not at issue. (ZHP Br. 35).[16] ZHP simply disputes the

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[15] ZHP's focus on *Sovulj v. United States* is even more perplexing because there, the "plaintiff d[id] not provide the court with a declaration, affidavit or direct statement from that doctor, nor does she provide the court with the doctor's findings" to establish the relationship between the missing x-ray and the adverse inference. No. 98 CV 5550FBRML, 2005 WL 2290495, at *5 (E.D.N.Y. Sept. 20, 2005), *on reconsideration*, No. 98-CV-5550 (FB), 2008 WL 11449125 (E.D.N.Y. May 14, 2008). Here, Plaintiffs have provided evidence closely tying Baohua Chen to the entire valsartan lifecycle through the recall and beyond. The direct and circumstantial evidence absolutely support the inference that Mr. Chen knew about the contamination and directed the cover up. ZHP's other cases on this issue are similarly distinguishable, and none of them involved a key witness refusing to appear for a court ordered deposition.

[16] After the Special Master rejected its request to postpone the issue until after its motion to reverse SMO 98, ZHP did not object to the reasonableness of Plaintiffs' requested attorneys' fees and costs before the Special Master, but instead "reserved" its rights to object later. (ECF 2726; ECF 2730; ECF 2737, at 9-11). This is a waiver since that was the time to raise the objection—ZHP cannot unilaterally alter the briefing schedule to suit its whims.

Special Master's award of any additional monetary sanction. (ZHP Br. 38). The starting point is the position taken by ZHP before the Special Master in the face of the even more devastating sanctions initially requested by Plaintiffs. In that context, ZHP advocated for a sanction of $50,000 per day to be paid to Plaintiffs, in opposing Plaintiffs' request for a default as the primary sanction. ZHP relied on this position in imploring the Court to consider lesser sanctions than a default, and prevailed at least in part on that position, and is thus estopped from changing its position now. *New Hampshire v. Maine*, 532 U.S. 742, 749 (2001) (holding that "judicial estoppel, 'generally prevents a party from prevailing in one phase of a case on an argument and then relying on a contradictory argument to prevail in another phase.'" (quoting *Pegram v. Herdrich*, 530 U.S. 211, 227, n.8 (2000)).[17] Specifically, ZHP's opposition to Plaintiffs' Rule 37 motion cited *In re Sealed Case,* 932 F.3d 915 at 932, 939-40 (D.C. Cir. 2019), and correctly described the case as "affirming civil contempt sanctions, including a daily fine of $50,000, against Chinese banks for

[17] ZHP's other cases are inapposite. In *Martin v. Brown*, "[t]he district court failed to explain the basis for the sanction amount." 63 F.3d 1252, 1263 (3d Cir. 1995). The Special Master here has yet to issue his sanctions amount, but he will presumably explain his basis for it. In *Barkouras v. Hecker*, the plaintiff only requested attorneys' fee and costs, so the issue of additional monetary sanctions was not raised. No. CIV.A. 06-366 (AET), 2007 WL 777664, at *7 (D.N.J. Mar. 12, 2007). In, *Lithuanian Com. Corp. v. Sara Lee Hosiery*, the magistrate judge declined to review the reasonableness of a request for attorneys' fee and costs, the district judge disagreed: "I find, however, that as a matter of law the award of expenses and attorneys' fees must be reasonable regardless of Sara Lee's actual expenses." 177 F.R.D. 205, 214 (D.N.J. 1997). Thus, the issue of additional monetary sanctions was not raised in that case either.

refusing to produce documents in compliance with a discovery order." (ECF 1900, at 34). ZHP conceded the propriety of those monetary sanctions and cannot now take the opposite position.

Moreover, ZHP admits that an additional monetary sanction would be permissible "to coerce ZHP to comply with any outstanding discovery." (ZHP Br. 35). ZHP skips the fact that it has ongoing discovery obligations in this litigation, and has repeatedly produced new though inadequate documents throughout the litigation of the motions discussed in this brief, including this Rule 37 motion. Thus, there is a legitimate purpose for the assessment of a monetary sanction.

CONCLUSION

For the foregoing reasons, it is respectfully requested that this Court affirm Special Master Order 98.

Dated: May June 17, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 17, 2024, I electronically filed a partially redacted version of this brief and the supporting certification of Adam M. Slater with the Clerk of the Court using CM/ECF system, which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL. In addition, I hereby certify that unredacted copies of foregoing document will be served contemporaneous to filing via email on the Court, Special Master, and ZHP's Defense Counsel, Jessica Davidson at Jessica.Davidson@skadden.com. The complete exhibits will be sent via FedEx to the Court via a thumb drive, and emailed to the Special Master and ZHP's Defense Counsel, Jessica Davidson at Jessica.Davidson@skadden.com.

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Attorneys for Plaintiffs

By: /s/ Adam M. Slater

Dated: Jue 17, 2024